IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:	**Romano, Jack W. et.al.**
Serial No.:	**10/730,297**
Filed:	**12/08/2003**
Group Art Unit:	**3761**
Title:	**Method and Apparatus For Converting Supplies and Reducing Waste**
Examiner:	**Michael G. Bogart**

Commissioner For Patents
Alexandria, VA 22313-1450

Honorable Commissioner:

In response to the detailed Office Action dated 06/21/2006, please enter into the record in regards to the above identified Patent Application the following:

The detailed office action dated 06/21/2006 has been carefully considered.

It is noted the rejection of claims 7-14 based upon Romano (US 2003/0079803 A1) is sufficiently overcome by the March 10, 2006 affidavit.

It is noted that claims 4, 17 & 18 are allowed.

In a conference call with the Examiner, Applicant requested clarification of the term "waist" found of page 4 of said office action. This was raised to make certain that the examiner meant waste, instead of "waist" as recited in the office action to prevent any confusion in the intrinsic record with the recited term waist found in the Goldberg reference. The Examiner clarified that waist was meant to read waste in said office action. Therefore, Applicant moves forward with this reply on the basis that the term waste replaces the term waist in said office action.

It is noted "The drawing dated 08 December, 2003 are acceptable for examination purposes only. Upon allowance, new formal drawings will be required. Applicant shall provide formal drawing's upon allowance along with payment made pursuant to a notice of allowance in this case.

In the claims please amend claim 7 to cancel I without prejudice and with a reservation of rights to re-enter such cancelled subject matter into any RCE or CIP contemplated by the Applicant is this case.

Claim rejections-35 USC 103

It is noted "The indicated allowability of claims 5, 6, 16, and 19-24, is withdrawn in view of the newly discovered reference(s) to Goldberg *et al.*(US 4,620,846; hereinafter "Goldberg"). Rejections based on the newly cited reference(s) follow"

Applicant believes the Examiner has erred in said stated "Withdrawal of Allowability". Applicant contends the Examiner has incorrectly drawn numerous factual aspects of the Goldberg reference in said office action which, inter alia, led to such 103 rejection in error. Applicant fails to find the requisite Graham factors in said office action, such Graham factors being required to prove the legal basis for forming the legal conclusion of a rejection based on 35USC 103. This reply, inter alia, rebuts said "Withdrawal of Allowability" on further merits of factual findings. This reply argues for the re-allowance of said "withdrawn" claims 5, 6, 16, and 19-24, by cogent technical explanation of actual facts based on the Goldberg reference, proper construing of the Goldberg reference in regards to said office action. This reply will show why combining the instant case and the Goldberg reference, renders the combination unsatisfactory for both intended purposes, how the said combination changes the principles of operation of both cases, and, how inoperable the combination would be for both intended purposes. Applicant contends, inter alia, no reasonable expectation of success can be found in the combination of the Goldberg reference and the instant case, and, because no expectation of success can be found in evidence on the merits of the Examiners proposed combination, no suggestion or motivation can be found in the combination of the applied references. Thus Applicant contends, based on the generality of the foregoing, and the following arguments that no legal basis to support a prima facie case of obviousness under 35 USC 103 has been established by the Examiner in said office action. The requisite Graham factors, inter alia, and any such supporting facts are lacking.

It is noted "This application currently names joint inventors. In considering the patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f), of (g) prior art under 35 U.S.C. 103(a)." Upon allowance of any claims in the instant case, the Applicant will examine the allowed subject matter under its 37 CFE 1.56 obligation at that time. Any pre-allowance determination would be provisional only, and not subject to any finality of a final office action in this case.

It is noted "Claims 5-14 and 19-24 are rejected under 35 U.S.C 103(a) as being unpatentable over Goldberg". The Applicant rebuts as follows.

The Office Action, page 3 line 8 recites "Regarding claims 5 & 6, Goldberg discloses a supply chain method comprising"

Applicant believes this comment is made in error. The Goldberg reference fails to disclose a supply chain method and fails to disclose a supply chain conversion, as does the instant case. The Goldberg reference discloses a medical procedure of introducing and or removing fluids from a patient,(irrigation and aspiration) however, there is no supply chain steps which achieve the supply chain effect recited in the instant case when compared to the Goldberg reference. The metes and bounds of the Goldberg reference relies on its factual "closed" procedure principles of operation. The purpose of the Goldberg reference is directed towards reducing infection. Goldberg defines the root cause of infection as

resulting from prior art systems being "open to the atmosphere". The factual means of achieving Goldberg's closed system solution is based on a closed multi-valved "manifold" apparatus and employing specific valve closing and opening sequences to employ the closed manifold apparatus in such a closed event sequences. The apparatus and methods of the Goldberg invention discloses the incorporation of such a manifold, which specifically operates against the operating principles of the instant case.

Office action incorrectly draws from the Goldberg reference

Office action page 3 line 9 recites "a) sealing (40) a liquid (e.g. irrigation fluid) in a container (20) by closing said liquid in said container (20) at manufacturing (col. 6, lines 3-22).

The Examiner incorrectly draws the following from the Goldberg reference:

a) there is no "liquid sealing" in the Goldberg reference (col. 6, lines 3-22).

b) there is no liquid at manufacturing in the Goldberg reference (col. 6, lines 3-22).

c) there is no liquid in container 20 in the Goldberg reference (col. 6, lines 3-22).

d) the examiner incorrectly draws that container 20(folded, dry, and empty at manufacturing and sealed to the manifold) corresponds with the aseptic/sterile liquid container of the instant case.

e) the examiner is confusing the recited "closed" system manufacturing process "sealing techniques"(bonding and heat sealing techniques) which occur prior to "sterilization" (nothing to do with liquids) with a hermetically sealing of a aseptic/sterile liquid inside a container as defined by the instant case, and with the supply chain conversion steps of the instant case which are employed at the point of consumption. The examiner confuses operations at manufacturing with supply chain container conversion steps at a point of consumption.

f) the examiner is confusing Goldberg's "closed manifold assembly." with the hermetically sealed sterile/aseptic liquid containers of the instant case-no correlation.

g) There is no "closing" of liquids at manufacturing of the Goldberg device.(col. 6, lines 3-22).

h)valve (40) has no liquid to seal at manufacturing-containers(20) are empty.

Office action page 3, line 11 recites "b) providing said liquid in said container (20) at a point of consumption"

The Examiner incorrectly draws the following from the Goldberg reference:

a) no liquid is provided in container 20. Container 20 is provided as a sterile, dry, empty, collapsed, folded, sealed unit fashion-no liquids involved at manufacturing.

b) there is no liquid consumption provided by container 20 because there is "no liquid in container 20 at manufacturing" provided for in the Goldberg reference.

c)container 20 is unrelated to providing liquid, therefore no consumption exists.

d)the examiner confuses container 20 with an irrigation container.

e)the examiner confuses container 20 with a dialysate container.

f)the examiner confuses liquid distribution/consumption with respect to the single sterile manufactured closed sealed manifold system of the Goldberg device.

g) container 20 is delivered empty, pre-bonded and/or heat sealed and compactly folded.

Office action page 3 line 12 recites "c) unsealing (40), said container (20) by removing said closure.

The Examiner incorrectly draws from the Goldberg reference:

a) the Examiner confuses the Goldberg manifold(s) valve (40) with the container of the instant case.

b) the Examiner incorrectly draws that valve (40) is apart of a container. Valve 40 is not a part of a container, therefore no container unsealing exists in the Goldberg reference. Valve (40) is a part of output port (30) and the manifolds of the various embodiments of Goldberg.

c)the examiner incorrectly draws that liquid exists in container (20).

d)the examiner incorrectly draws that Goldberg discloses a closure for container (20).

e)the examiner errs in comparing the empty container (20) with the full container of the instant case.

f)the examiner defeats the "closed" system requirement of Goldberg by incorrectly suggesting in the office action, the unsealing container (20) at this point "the opening up the intended closed system to the atmosphere", contrary to the teachings of Goldberg, causing infection contamination and leakage. The examiners suggestion also causes a breech in the reliable leak-proof seals which form impermeable barriers to contamination and infection (col. 6 lines 7-10, col 6, lines 15-19). Also contrary to the intended purpose, principles of operation, and are unsatisfactory for the intended purpose of the Goldberg reference, leaving no expectation a closed system as required by Goldberg following such suggestion by the Examiner.

g)the Examiner incorrectly draws that container 20 has a valve (40).

h)the Examiner incorrectly draws an unsealing/sealing step could be carried out when container 20 has no closure.

i) whereas the valve (40) is part of a sealed leak proof unit, sealed at manufacturing, the Examiners suggested removing step would require a destructive disarticulation of the components, which have been sealed from the beginning, prior to sterilization at manufacturing. The Examiners suggestion renders the Goldberg manifold apparatus broken, leaking, contaminated and unsealed and destroyed and inoperable for its intended purpose.

j)the examiner incorrectly draws that a sealed in valve (40) is removable, without destroying the heart of the principle (the closed system) of the Goldberg reference leading to leaking, contamination, and breaking the impermeable leak-proof barrier as required by Goldberg.

k) valve (40) is sealed between output port (30) and manifold at manufacturing by a manufacturing operation prior to sterilization which is not commensurate with the supply chain steps in the instant case as incorrectly drawn by the examiner. (The Goldberg reference teaches, inter alia, a manifold having separately valved input and output ports.(Fig 1-310 #'s 10, Fig 4, #10, Fig. 5 #130, Fig 7, 7a, 7b, 8, 8a, & 9-#210(belt), Fig 10 & 11, #340(dialysis belt) and Fig 12 & 13 #380(the belt).) used solely for the purposes of introducing fluids and removing fluids from a patient.(No supply chain conversion disclosed by Goldberg).

l)the Examiner has erred in combining Goldberg's sterile manufacturing operations with the supply chain steps of the instant case. Such a suggestion is incorrect.

Office action page 3, lines 13 & 14 recites "d) sealing a vacuum draw path (152) with said container (20) by coupling said path (152) with a fluent waste collection system (150, 152, 154, 50, 10).

The Examiner incorrectly draws from the Goldberg reference:

a) sealing the Goldberg container 20 occurs at manufacturing and prior to sterilization using manufacturing techniques to join output port 30 to container 20. (Not a supply chain conversion step of the instant case). No vacuum draw path disclosed in the manufacturing operations as specifically defined in the Goldberg reference which specifically defines what aspect of the Goldberg device are a "single sealed unit from the beginning".

b) Goldberg discloses no causal connection between container 20 and draw path 152.

c) No draw path 152 exists at a suction device 150 terminating at a valved input port 50, just a drainage line which periodically empties suction device 150. The examiner confuses an intermittent

(periodic drainage line-Figure 4) , strictly opened and closed with valves, with a continuous flow vacuum draw path of the instant case.

d) there is no vacuum draw emanating pulling forces from container 20.

e) container 20 is manufactured only with access connection to *single output port* making it virtually impossible for a force to be drawn from container 20 and at the same time the same port force drawing fluid material into container 20. The Examiner incorrectly draws a comparison which suggests an impossibility of physics.

f) there is no draw force existing in the Goldberg reference.

g) a drainage line of Goldberg (152) is not a draw force.

h)Goldberg discloses "only" a drainage line going "towards" the manifold.

i)there is no force emanating from container 20 in the Goldberg reference.

Office action page 3, line 15 recites "e) drawing said fluent material waste into said container.

The Examiner incorrectly draws from the Goldberg reference:

a)there is no drawing disclosed from container 20. Drawing occurs with a remote negative force which does not exist in figure 4, but is found in the instant case.

b) the Examiner incorrectly drew that suction device (150) provided (it does not) drawing forces. If suction device 150 provided drawing forces on container 20, container 20 would shrink under the drawing force, any dialysate in container 20 would reverse direction and the dialysate would return to the suction device 150. The Examiner incorrectly drew reverse principles of physics in said office action based on incorrect scientific theory.

c)container 20 would re-fold under a negative force as described by the examiner, which is contrary to the container 20 being unfoldable into its full drainage capacity as required by Goldberg.

d)container 20 is soft collapsible and folded and would shrivel up under the drawing step described by the examiner moving dialysate into the opposite direction of the Goldberg principle.

e)dialysate would be left in the peritoneal cavity leaving the patient sick.

f)the examiner incorrectly draws that the input ports and output ports are open at the same time in order for the flow through to occur in order to meet the examiners suggestion.

g)The examiner has incorrectly drawn from Figure 4 of the Goldberg reference, that a "drawing" force emanating from device 150 would create a positive flow force moving materials towards valve 50, through the manifold and into container 20. This is scientifically incorrect. A drawing force emanating from device 150 (as suggested by the examiner) would create a negative flow force moving dialysate in the opposite direction from container 20, back through valve 30, back through manifold 10, back through valve 50, back through drainage line 152 and back into suction device 150. This defeats/destroys the purpose of Goldberg attempt to create a closed system that can now creates an unlimited capacity peritoneal dialysis system.

h)the Examiner incorrectly draws from the Goldberg reference that the multiple valving requirements requisite to keeping the Goldberg device "closed" would provide for an open flow path that a vacuum draw would continually require/need to draw fluid from a remote source from, and then into a container.

Office action page 3 lines 16 & 17 recites "f) unsealing (40) said path by disconnecting said container (20) from said vacuum draw path (152) and said waste collection system (150, 152, 154, 50, 10),

The examiner incorrectly drew from the Goldberg reference.

a)there is no unsealing by valve (40). The valve is always closed to maintain the sterility and integrity of the closed system.(Never open to the atmosphere-preventing infection.)

a)there is no unsealing step carried out by disconnection of container (20). Container (20) is removed only after valve (40) is always closed.

b)valve (40) is always closed (maintaining the closed system)

c)the said path described by the examiner is not present in the Goldberg reference.

d)the vacuum draw path (152) is incorrectly defined by the examiner.

e)the Goldberg reference specifically refutes the examiners suggestion by requiring the valve (40) to always be closed, prior to the removal of container (20).

f)the examiner erred in the suggestion that there is a causal connection between valve (40) and removal of container (20) resulting in an impact on a path. Goldberg unequivocally prevents the examiners suggestion by the requirement of "never opening the system up to the atmosphere" by the operation of valve (40) which is separated from the container by the output port.

g)if no vacuum draw path exists in Goldberg, there is no disconnection of container (20) from it because it does not exist in the reference.

Office action page 3 lines 18 & 19 recites " g) sealing said container (20) with a closure (40) for containment and disposal of said fluent waste material (Abstract col. 4 lines 16-50, col 6. lines 37-48, fig. 4 infra)

The examiner incorrectly drew from the Goldberg reference:

a)there is no container sealing operation in the Goldberg reference. Goldberg defines a severing operation, which is not a sealing operation. Such a severing operation would not a container 20 and it would not seal the output port 30, just break the single sealed unit, which has been sealed from the beginning at manufacturing.

b)Goldberg does not disclose a closure for container 20.

c)in order for valve (40) to function as a closure ((as suggested here by the examiner),(after disconnection as suggested by the examiner page 3 line 16-office action section f,)) for container 20, it would be required to be destructively removed (40) from the manifold 10, along with its associated output port 130. Clearly Goldberg does not disclose such destructive activity which would destroy the principles of operation, and render the manifold (always closed manifold system now open to the atmosphere) unsatisfactory for its intended purpose and significantly change the principles (always closed-never open to atmosphere) of operation of Goldberg.

d)no container (20) containment method or apparatus exists in the Goldberg reference.

e)no possibility of fluent material containment exists in the disposal of such material as suggested by the examiner. The Goldberg reference lacks the requisite disclosure for containment of anything after the severing operation as defined in the reference. Valve (40) is permanently sealed to the output port at manufacturing by bonding and/or heat sealing techniques prior to delivery.

The Applicant finds cogent technical reasoning lacking in the foregoing Examiner's remarks, inter alia, the Examiners incorrect drawing and attempted comparison of events disclosed at manufacturing in the Goldberg device with the supply container conversion events as disclosed and claimed in the instant case leaves no scientific or technical foundation of facts that could lead the examiner towards a proper legal conclusion of prima facie obviousness under 35 USC 103.

"The rational to support a rejection under 35 USC 103 may rely on logic and sound scientific principle." *In re Soli, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). "* However, when an Examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided". *In re Grose, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979).*

Evidentiary support is lacking with respect to the Examiners remarks, and the 103 rejection. It is the burden of the Examiner to establish why one having ordinary skill in the art would have been led to the claimed invention by the express teachings or suggestions found in the prior art, or by implications contained in such teachings or suggestions. *In re Sernaker, 702 F.2d 989, 995, 217 USPQ 1, 6 (Fed. Cir. 1983).*

The Examiner has not explained what the motivating force is, in the Goldberg reference that would lead an artisan who is solely dependent on a completely closed valved manifold device, to be combined with the open container conversion supply chain method of the instant case. The examiner has not explained what the motivating force is that would lead an artisan who requires an open continual fluent material flow container conversion supply chain method to use a completely closed manifold device which is completely closed requiring sequential valve opening and closing which impedes and obstructs any continual draw force, and flow. The Goldberg device would not allow the force of the instant case to continually draw from the container due to the Goldberg requisite valve obstruction as required to keep the manifold closed.

No legally recognizable heart of the Goldberg reference exists in the Examiners remarks regarding claims 5 & 6. *When determining obviousness, the claimed invention should be considered as a whole; there is no legally recognizable heart of the invention. Para-Ordinance Mfg. v. SGS Importers Int'l, Inc., 73 F.3d 1085, 1087, 37 USPQ2d 1237, 1239 (Fed. Cir. 1995), cert denied. 117 S. Ct. 80 (1996) citing W. L. Gore & Assoc., Inc. v. Garlock, Inc. 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983) cert. denied, 469 U.S. (1984).*

Applicant contends based on the forgoing many technical corrections, inter alia, the Examiner has not provided evidentiary support for arguments made in the office action. No prima facie case of 103 obviousness can be explained based on incorrectly drawing on a reference and incorrect technical reasoning as has been directed at claims 5 & 6 of the instant case. The Goldberg reference teaches away. *It is improper to combine when the references teaches away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir 1983).*

Applicant further contends that it is quite clear from the following recitation of fact (#1-#21 infra) that the Goldberg reference can only be understood to disclose a manifold system that is intended as a closed manifold system, and is disclosed to be a closed manifold from initial manufacturing prior to sterilization, and continuing to be a closed manifold system even after the step of severing and removing a container from the manifold(by closing valve (40) which is separate from the container 20.. *Considering a situation where a patents disclosure makes crystal clear that a particular (i.e. narrow) understanding of a claim term(the closed manifold system is manufactured closed, always closed, and never open to atmosphere) as an essential element of (inventor's) invention. Tronzo V. Biomet, 156 F3d at 1158-59, USPQ2d at 1833 (Fed. Cir 1998).* The manifold system of the Goldberg reference would impede the continuous draw force requirements of the instant case and render it unsatisfactory for its intended purpose because the valves of the Goldberg reference and the closed system requirements associated therewith would impede the open flow through requirements of the instant case. *The proposed modification cannot render the prior art unsatisfactory for its intended purpose. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).* Any such modification as described by the examiner would render the Goldberg reference unsatisfactory for it intended purpose, and would make the Goldberg device and open device, which changes the principles of operation of Goldberg. *The proposed modification cannot change the principle of operation of a reference. If the proposed modification or combination of the prior art would change the principle of operation of the prior art*

invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Riatti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

The open system requirements of the container conversion supply chain methods of the instant case would render the Goldberg reference inoperable for its intended purpose whereas the Goldberg reference is only operable to the extent that the system is kept closed to prevent infection, contamination, leakage etc., from its initial manufacturing until after container severance. The instant case utilizes a step whereby a container, once emptied is engaged in an open condition and then is involved with sealing a vacuum draw path. *If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modifications. In re Gordon, 733, F.2d, 221 USPQ 1125 (Fed. Cir. 1984).*

Applicant further contends it is quite clear from the following recitations of fact (# 22-#138 infra) that the Goldberg reference can only be understood to be operated as a closed system relying on the manifold apparatus and valve means defined therein to achieve such a closed system throughout its uses. *Considering a situation where a patents disclosure makes crystal clear that a particular (i.e. narrow) understanding of a claim term (the closed manifold system is always operated to be a closed manifold system including specific sequences of valve opening and closing obstructing flow as required to maintain closed systems(opening and closing valves) that is required in order to keep the closed manifold system closed) as an essential element of (inventor's) invention. Tronzo V. Biomet, 156 F3d at 1158-59, USPQ2d at 1833 (Fed. Cir 1998).*

The following #1-138 construes facts found in the Goldberg reference that the operation of a closed system supports of the arguments herein, inter alia, to prove facts related to the "closed manifold system" invented by Goldberg et al. These factual findings are found in the Goldberg specification which recite the requisite requirements at manufacturing defining required manufacturing operations (sealing techniques-bonding and/or heat sealing) carried out, prior to sterilization, prior to shipping, for achieving said means of providing such "closed manifold system" Fact finding found in the numbered recitations #1-#138 infra.

Applicant stresses the Examiner refrain from confusing Goldberg's recited language (defining manufacturing operation types of manifold bonding & heat sealing techniques performed by manufacturing technicians and manufacturing equipment and machinery and carried out at manufacturing, to manufacture the Goldberg device), with the instant cases sealing and unsealing steps taught by the instant case which are carried out at the point of consumption defining container conversion at the point of consumption and carried out by the consumer to impact the supply chain events as disclosed in the instant case. Any such point of consumption steps disclosed by the instant case, and combined with the Goldberg reference would break Goldberg's required sterile procedure in half rendering such a procedure a failed and damaging act. Any such combination of Goldberg and the instant case would provide closed to open and open to closed by the sealing and unsealing methods operations of taught by the instant case, leaving no heart of the Goldberg reference intact. The sealing and unsealing in the instant case defines supply chain event steps performed by the consumer/customer, and the Goldberg reference defines manufacturing operations performed by employees of the manufacturer, prior to the Goldberg device leaving the factory. Two completely different events, different processes, different performers at different times such differences not commensurate in scope, and, such differences having distinctive metes and bounds.

With respect to Claim 1 of the Goldberg reference, the elements (first manifold, second manifold, plurality of separately valved input ports, said receiving means including a plurality of containers

individually coupled to the second manifold, said first and said second manifold being provided in a longitudinally divided, elongated flexible tubular member that is sized to fit around the abdomen of a human subject), *inter alia*, provide elements which may be omitted (from the combination of Goldberg and the instant case as has been suggested by the examiner), yet the instant case will still retain its function. *Omission of an element with Retention of the Elements Function Is an Indicia of Unobviousness. In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Note that the omission of an element and retention of its function is an indica of unobviousness. To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496, (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

With respect to claim 2 of the Goldberg reference, and the suggested Goldberg/Romano et al. combination made by the Examiner, the instant case will still retain its function without use of the claim element/limitation "the containers are collapsible for compact storage adjacent the second manifold". The instant case will retain its function without said element of claim 2 of the Goldberg reference. *Note that the omission of an element and the retention of its function is an indica of unobviousness. In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Note that the omission of an element and retention of its function is an indica of unobviousness. To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496, (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

With respect to claim 3 of the Goldberg reference, and with respect to the examiners suggested combination of the Goldberg reference with the instant case, the instant case will retain its function without steps a-g of claim 3 of the Goldberg reference. Note that the omission of an element and the retention of its function is an indica of unobviousness. *In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Note that the omission of an element and retention of its function is an indica of unobviousness. To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496, (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

With respect to claim 4 of the Goldberg reference, and with respect to the Examiners suggested combination of the Goldberg reference with the instant case, the instant case will retain its function without steps a-h of claim 4 of the Goldberg reference. Note that the omission of an element and the retention of its function is an indica of unobviousness. *In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Note that the omission of an element and retention of its function is an indica of unobviousness. To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496, (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

With respect to claim 5 of the Goldberg reference, and with respect to the Examiners suggested combination of the Goldberg reference with the instant case, the instant case will retain its function without steps a-h of claim 5 of the Goldberg reference. Note that the omission of an element and the retention of its function is an indica of unobviousness. *In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Note that the omission of an element and retention of its function is an indica of unobviousness. To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496, (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).*

Heart of Goldberg facts teaching manifold system closed bonding/sealing

#1--Column 3 lines 21-32. One of the principle advantages of this improved drainage device and method is that each of the multiple containers can be filled and removed from the manifold **without ever opening the device to atmosphere during use**. When drainage begins, the entire device complete with a number of containers already attached to the manifold is a **sealed sterile unit.** ***Containers are sequentially filled*** and removed but the removal of individual containers is performed **only after the respective valve has been closed and the container isolated.**

#2--Column 3 line 44-49. Furthermore, each of the individual containers can be made of a ***collapsible material which can be folded into compact*** volume for storage before use. In this way a compact drainage device can be made which is readily stored and transported before use and is relatively low in bulk during use.

#3--Column 3 line 67-Column 4 line 1. Preferably, each container is provided with a ***dry sterile catheter*** and each capped input port is also ***dry and sterile***.

#4--Column 5 lines 31-46. this drainage manifold 10, is generally tubular in structure which is provided with a valved input port 50 and four valved output ports 30. The ***collapsible thin wall*** container 20 is ***sealed to each of the output ports 30***. In Figure 1, three of these containers 20 are shown ***collapsed and folded*** for storage into ***small packets*** and one of the containers 20a is shown unfolded ready to receive fluid from the manifold 10. Preferably, each container if formed of a flexible plastic material such a vinyl polyethylene or some other suitable material. The support net 90 is provided which can be positioned around an unfolded container 20a, by means of a hook 92 from manifold 10. The net 90 serves to support a major part of the weight of fluid contained in container 20a thereby permitting the use of *thin low bulk materials for the container 20.*

#5--Column 5 line 65-Column 6 line 2. Each of the valved output ports 30 includes a valve 40 which ***operates to selectively seal the port 30***. Each ***valve 40 includes a flange 32 sealed to the manifold 10***. Each output port 30 extends into the interior of the manifold 10. Each container 20 includes a narrow ***neck region 24 which is sealed to one of the input ports 30.***

#6--Column 6 lines 3-23. Then ***manifold*** is preferably formed from an ***extruded tube*** of vinyl of some other suitable plastic. Standard push pull valves such as valve model 320TE manufactured by Hawlkey

of Paramus NJ are used to ***reliably seal the associated input port 50*** and output port 30 against contamination leakage and infection. The entire device, including the manifold 10, the foldable containers 20, and the input port 50 **forms a single sealed unit which is assembled under standard clean room conditions and then sterilized for use.** *Standard adhesive or heat* ***sealing techniques*** can be used to *bond* the manifold 10 the containers 20, and the ports 30,50 together to form a **sealed leak proof unit.** Whatever sealing technique is used, however should provide **reliable leak proof seals which form impermeable barriers to contamination and infection.**

#7--Column 6 lines 27-28. **As mentioned, the device is originally sterilized** with input port 50 closed and capped.

#8--Column 6 lines 33-36. An alternative embodiments, the drainage catheter can be sealed to the input port 50 during the manufacturing process and the entire assembly including the catheter can be sterilized as a unit.

#9--Column 7 lines 16-23. As before, the central manifold 10 is provided with a valved input port ***50' and four output ports 30' each of which is connected to a collapsible container 20'***. The input port 50' is adapted to connection with a urinary drainage catheter 62' **and the entire assembly, including the manifold 10', the container 20', and the input port 50' is manufactured as a single sealed unit which is sterilized prior to use.**

#10--Column 7 lines 44-47. Once again, the drainage device includes a manifold 10", a valve input port 50", and several containers 20" ***connected*** to the manifold 10" by valved output ports 30".

#11--Column 7 lines 51-59. The suction device 150 can be a conventional ***closed*** wound suction device and is operated in a conventional manner except that the suction device 150 is periodically ***emptied*** through the manifold 10' into one of the attached containers 20' ***without ever opening*** **either the suction device 150 of the manifold 10' to the atmosphere. As before the closed system drainage device operates to reduce contamination and results in retrograde infection of the patient.**

#12--Column 8 lines 24-29. This irrigation manifold is manufactured under standard clean room conditions. The output port 132 is then closed by means of valve 136 and capped. Each of the input port 140 is capped and closed by means of the associated valve 150 and then the *entire sealed manifold assembly is sterilized*.

#13--Column 9 lines 42-65. A set of eight containers 220 is mounted on each side of the bottom portion of belt 210 by means of conduit 230 equipped with valve 240. These containers are preferably ***thin plastic bags*** formed of vinyl or polyethylene, for example, which can be compact and ***folded*** as shown in Figure 6 prior to use. **Each bag is sealed to the lower end of the associated valve 240 which is in turn sealed to the conduit 230 extending from the belt 210. Adhesives or heat sealing techniques may be used to secure the containers 220, valves 240, conduits 230, the belt 210 to form a single sealed leak proof unit which provides an impermeable barrier to contamination and infection.** Each of the containers 220 is ***originally folded*** into and small packet adjacent the associated valve 240. The use of these container will be explained below. Here it is enough to know that each container can be ***unfolded*** to its full size as shown by the unfolded container 220a.

#14--Column 10 lines 4-9. A set of eight input ports 250 is mounted on each side of the top of the belt 210. Each port 250 is a tubular structure which is provided with a valve 250 and a snap on cap 270. **Once again the port 250, valves 260, and belt 210 are bonded together to form a single sealed unit which forms an impermeable barrier to infection.**

#15--Column 10 lines 19-24. Figure 7b shows a cross section of the belt 210 and the flattened section 218. In this region the tubular belt 210 has been flattened and the two opposed sides of the belt have been **sealed** together to **prevent leakage** from or contamination of the belt 210 near the end section 216, 218.

#16--Column 10 lines 29-34. The belt catheter 320 passes through an opening 312 in the belt 210 and is bonded to the belt 210 vial a flange 322. Once again, it is important that *leak proof seal* be formed to prevent contamination or infection and heat sealing or adhesive *bonding techniques* may be used.

#17--Column 10 lines 47-66. Figure 9 shows a cross sectional view of the belt 210 showing the internal arrangement of port 250 and the container conduits 230. Each conduit 230 penetrates and is in fluid communication with the central volume 300. It is provided with an external flange 232 which is ***sealed*** against the outside of the belt 210. In order to increase the packaging density adjacent conduits 230 are staggered by about 20 degrees. This permits the ***folded containers*** 20 to overlap as best seen in Figure 6. **Each container 220 defines a narrow neck region 224, which is *sealed* to the lower portion of the associated valve 240. Each of the valves 240 is an *on-off valve which completely seals off* the interior of the belt 210 from infection when the valve 240 is closed.** In the presently preferred embodiment, low bulk, push pull valves are used in which the valve is used to open and pushed to close. Such valves are readily available in standard components valve model 320TE manufactured by Hawlkey-Roberts of Paramus NJ. is one example of such a valve.

#18--Column 11 lines 7-18. The belt 210 should be *assembled in a clean room* and then sterilized prior to use. Utilizing *standard manufacturing practices* for medical devices as outlined by the Food and Drug Administration. It should be understood that when belt 210 containers 220, and port 250 are assembled all valves 240, 260 are closed and the belt catheter 320 is *sealed prior to sterilization*. In this way the belt is delivered as a *single sterile unit ready for use*. In use, belt 210 acts as a manifold though which dialysate can be introduced into and removed from the peritoneal cavity with reduced incidence of infection.

#19--Column 11 lines 25-29. First a container dialysate (not shown) is coupled via a tube to one of the valves 260. **The valve 260 will be *dry and sterile* for it has been capped since its initial sterilization.**

#20--Column 11 line 66-Column 12 line 9. When proper precautions are taken to assure that each dialysate container is sterile, this use of each input port is only believed to reduce the incidence of infection. **Furthermore since all drainage containers 220 are sealed in place from the beginning, dialysis drainage is accomplished *without ever opening* the belt 210 to atmosphere. In this way , infection associated with drainage is reduced.** The belt 210 has been designed to minimize infection of the subject from dialysis contamination either when introduce into the subject or when drained.

#21--Column 12 lines 14-18. ***Only after*** each of the port can container has been used will the belt be replaced with a **new belt complete with a new set of sterile ports and folded containers.**

Heart of Goldberg facts teaching maintenance of a closed manifold system in use

#22--Abstract lines 2-4. The fluid receiving manifolds include a plurality of separately valved containers **sealed** to the manifold.

#23--Abstract lines 4-7. Each container is **filled in series** via the manifold and associated **valve is closed *before* the container is removed** from the manifold for disposal.

#24--abstract lines 7-8. Thus a **closed drainage system** is provided.

#25--Abstract line 10. Preferably **each port is used only once**.

#26--Abstract line 11-12. In each case the **port is kept closed *until*** it is coupled to a source of fluid and it **is re-closed *before*** the source of fluid is disconnected from the port.

#27--Abstract line 14. In this **contamination is further reduced**.

#28--Column 1 lines 14-15. The present invention is directed to improved devices and methods for **reducing infection**.

#29--Column 1 line 25-27. In these and other similar situations the **continued sterility of all associated devices used for.**

#30--Column 1 line 31-33. It is well recognized that conventional drainage devices are a prime source of infection of catheterized patients.

#31--Column 1 lines 37-38. and infection then ascends in a retrograde manner.

#32--Column 1 line 40. Such retrograde infection.

#34--Column 1 line 60-64. Retrograde infection in drainage devices is in many cases attributable to the fact that conventional drainage devices **are open systems** which are repeatedly open to atmosphere and therefore subject to contamination during use.

#35--Column 2 lines 1-5. After the evacuator becomes filled, it is emptied for re-use by removing the cap and expelling the collected fluid in the outlet. During this operation the anterior of the evacuator is exposed to the atmosphere and contamination of the evacuator may result.

#36--Column 2 line 10. This valve operates to close the outlet at all times.

#37--Column 2 line 14. But they are **not true closed systems** because the evacuators are periodically opened for purging it is still possible for them to be contaminated as a source of infection.

#38--Column 2 line 19. For **reducing the incidence of retrograde** infection due to contamination of drainage devices.

#39--Column 2 line 23. A second source of patient infection is contamination of devices for introducing fluid into the body.

#40--Column 2 line 33. In this approach the indwelling catheter is connected to and then disconnected from a number of container in **sequence**. The same connection point of the containers is **repeatedly brought into contact** with the dialysate and then exposed to the atmosphere.

#41--Column 2 line 38 & 40. This **repeated wetting** and exposure to atmosphere is believed to contribute to the contamination of the catheter and associated infection.

#42--Column 2 line 42. May become infected as they are connected to and disconnected from a number of containers of irrigation fluid in succession.

#43--Column 2 line 44. Thus a second important object of the present invention is to provide improved devices and methods for introducing fluid into human and animal subjects with reduced possibility of contamination thereby **improving sterility and reducing infection**.

#44--Column 2 line 53. which are **less susceptible to contamination** infection than devices and methods of the prior art.

#45--Column 2 line 56. According to a first feature of this invention, a **completely closed drainage** device is provided which the interior of the device need ***never be opened to the atmosphere*** during use.

#46--Column 3 line 1. and individual conduits are provided with valves which can be positioned to ***close off*** **the conduits therefore** ***isolating*** **the associated containers** from the manifold. Each of the conduits are ***severable at a point between the associated valve and the container.***

#47--Column 3 line 11. The associated valve is then **closed in order to isolate** this fluid filled container from the manifold.

#48--Column 3 line 14. The fluid filled container is then removed.

#49--Column 3 line 17-20. The separate container are then **sequentially filled** and then removed until either all the containers are filled or drainage from the subject is discontinued.
#50--Column 3 line 24. **Without ever opening the device to atmosphere during use.**

#51--Column 3 line 27-30. Containers are ***sequentially*** **filled and removed** but the removal of the individual containers is ***only*** performed ***only after*** **the respective valve has been closed** and the container isolated.

#52--Column 3 line 30-31. Preferably **each valve is capped and further sealed** from the environment.

#53--Column 3 line 35. Since the drained body fluid is **removed in a series** of containers.

#54--Column 3 line 44. Furthermore each of the individual containers can be made of ***collapsible*** **material which can be** ***folded*****.**

#55--Column 3 line 55. According the a second feature of this invention, an improved device for introducing fluid into the human body.

#56--Column 3 line 60-64. Each port is provided with a separate valve by means by which the **port may be isolated** form the manifold. Each port is preferably provided with a cap for **sealing the port** when not in use.

#57--Column 3 line 67-column 4 line 1. Preferably each container is provided with a **dry sterile** catheter and **each capped input port is dry and sterile.**

#58--Column 4 line 3-5. After the catheter is connected, the associated **valve is opened and fluid is allowed** to flow from the container into the body.

#59--Column 4 line 7. **When the container is emptied a second container is then connected** to the manifold via a second port.

#60--Column 4 line 8. In each case the associated port **valve is only opened after the container** has been connected to the port **and the valve is closed before** the container is removed. Preferably **each port is only used once**.

#61--Column 4 line 14. **by *never* using a port twice.**

#62--Column 4 line 27-31. the dialysis manifold is coupled to the peritoneal cavity of the subject and a **separate containers** are used as previously described to remove dialysis from the manifold ***without ever opening it to the atmosphere*.**

#63--Column 4 line 36. In this embodiment of the invention, containers of dialysate are **sequentially coupled** to different ports as before **each port is used only once to reduce infection.**

#64--Column 4 line 42. Instead the **container is left connected to the port** and the dialysate is then drained from the peritoneal cavity to the same container from which it came.

#65--Column 4 line 45. It is ***only then* that the container is removed** from the port.

#66--Column 4 line 46. This embodiment provides the important advantage that the total drainage capacity of the manifold is **no longer limited by the number of containers that can conventionally be stores** adjacent the manifold.

#67--Column 4 line 64. Figure 4 is a schematic view of a **drainage manifold coupled to a closed wound suction device.**

#68--Column 5 line 3-5. preferred embodiments of both the **closed drainage feature** and the multiple input port feature of the present invention.

#69--Column 5 line 33-34. A ***collapsible* thin walled** container 20 is sealed to each of the output ports.

#70--Column 5 line 36. **are shown collapsed and folded**.

#71--Column 5 line 42. can be positioned around an **unfolded container 20a.**

#72--Column 5 line 58. both ends of the manifold 10 are **sealed**.

#73--Column 5 line 59. Input port 50 includes a valve 60 which operates to ***selectively*** **seal the port** 50.

#74--Column 5 line 65. Each of the valved output ports 30 includes a valve 40 which **operates to** ***selectively*** **seal the port** 30.

#75--Column 6 line 1-2. Each container 20 includes a narrow neck region 24, which is **sealed to** one of the input ports 30.

#76--Column 6 line 8. **Reliably sealed,** the associated ports 50.

#77--Column 6 line 9. The entire device including the manifold 10, the foldable containers 20, and the input port 50 forms a *single sealed unit which is assembled* in a standard clean room conditions and the sterilized prior to use.

#78--Column 6 line 15. Whatever *sealing* technique is used, however, should provide *reliable, leak proof seals which from impermeable barriers* to contamination and infection.

#79--Column 6 line 20. Which is *closed and capped during manufacturing* process to ensure the continued sterility of the device.

#80--Column 6 line 23. In use the drainage device of Figures 1 & 2 functions as a **closed system** which receives fluid drained from the body.

#81--Column 6 line 26. **Without ever opening the drainage device.**

#82--Column 6 line 27. As mentioned, **the device is originally sterilized** with the **input port 50 closed and capped**.

#83--Column 6 line 33. In alternative embodiments, drainage catheter can be *sealed* to the input port 50 *during manufacturing, process entire assembly* the including the catheter can be sterilized as a unit.

#84--Column 6 line 37. **After** the input port 50 has been mated.

#85--Column 6 line 44. The associated valve 40 is **closed.**

#86--Column 6 line 49. Each of the containers 30 is preferably **filled in sequence so that no more than one container is receiving drained fluid at any given time.**

#87--Column 6 line 51. In each case the associated **valve 40 is closed** before the container is ***severed*** **thus the manifold is *never* opened to atmosphere** or contamination ***after*** it has been connected to the source of body fluid.

#88--Column 6 line 55. Large quantities of fluid can be drained over an extended period of time **without ever opening the system to atmosphere.**

#89--Column 6 line 58. The **closed system drainage device** of this invention.

#90--Column 7 line 5. Thus, this embodiment provides a **simple closed system drainage** device.

#91--Column 7 line 9. It is preferable to **use a closed system drainage device.**

#92--Column 7 line 12. Now turning to Figure 3 the **closed system drainage** device is well suited for use with ambulatory patients.

#93--Column 7 line 16. As before a central manifold 10' is provided with a valved input ort 50' and four valved output ports 30' each of which is connected to a **collapsible** container 20'.

#94--Column 7 line 41. Figure 4 shows a schematic view of a **closed system drainage** device of this invention ***arranged*** to receive drainage material from a **closed wound suction device.**

#95--Column 7 line 51. The suction device 150 can be conventional **closed wound suction device** and it is operated in the conventional manner except suction device 150 is **periodically emptied** through the manifold 10" into one of the attached containers 20" ***without ever*** **opening either the suction device *or* the manifold 10" to atmosphere**. As before the **closed system** drainage device ***operates to reduce*** contamination and resulting retrograde infection to the patient.

#96--Column 7 line 60. It should be apparent from the foregoing discussion that the **closed system drainage device** of this invention can be used either **with or without suction** devices in either fixed installation or portable embodiments.

#97--Column 8 line 3. In general these **devices include multiple separately valved input ports** each of which is preferably **used only once**. These ***devices and methods*** are well suited for **bladder irrigation, wound irrigation and other situations where sterile fluids are introduced to the** body.

#98--Column 8 line 14. This output port 132 is provided with a check valve 134 oriented to prevent fluid from entering the manifold 130 via the output port 132, and the **valve 136 which operates to selectively close the output port 132.**

#99--Column 8 line 26. The output port is then closed by means of the valve 136 and capped, each of the input ports 140 is capped and closed by means of the associated valve 150, and the *entire sealed manifold assembly is sterilized*.

#100--Column 8 line 31-39. In use the output port 132 is coupled to an irrigation catheter such as a bladder irrigation catheter, for example. As before, the catheter can be made an integral part of the output port 132 or the port 132 can be mated with a suitable catheter either before or after the catheter has been inserted into body. A container of irrigation solution **is then connected** to one of the input ports 140 and the associated **valve 150 is opened to *allow*** the solution to pass into the **manifold** 130 and out the output port into the body.

#101--Column 8 line 41. When a second container of nutrient is needed the valve 150 on the **input port 140 connected to the first container is closed** and the first container is removed.

#102--Column 8 line 44. Then the second container is coupled to a **fresh input port 140** that has not been previously used and the process is repeated. **Each input port is preferably used *only* *once*** to reduce the incidence of infection.

#103--Column 8 line 51. The multiple input port feature of the invention is not restricted to use in irrigation. It can be used in many situations where fluid from multiple sources must be introduced into the body **under sterile conditions**.

#104--Column 8 line 57. In each application the size of the manifold and the size and the number of input and output port should be chosen to fit the intended use.

#105--Column line 63. In this embodiment the output port is nothing more than the junction between the manifold and the catheter and the output port valve can be eliminated. This alternative embodiment is well suited for both collecting samples of a body fluid as well as introducing fluid into the body.

#106--Column 9 line 1. Referring now to Figure 6, both the multiple valved container feature of the invention and the multiple valved input port feature of the invention can be used together in a **manifold for peritoneal dialysis**.

#107--Column 9 lines 6-41. Includes features of the **garment** aspects of the belt.

#108--Column 9 line 47. Each **bag is *sealed*** to the lower end of the associated valve 250 which is in turn ***sealed*** **to a conduit 230** extending from the belt 210.

#109--Column 9 line 52. To form a *single sealed leak proof unit* which provides an impermeable barrier to contamination and infection.

#110--Column 9 line 57. Here it is enough to note that each container can be **unfolded to its full** size which is shown by the unfolded container 220a.

#111--Column 10 line 8. Once again the ports 250, valves 260 and belt 210 are *bonded* together to form a *single sealed unit* which forms an impermeable barrier to infection.

#112-Column 10 line 23. **have been *sealed* together to prevent** leakage from or contamination of belt 210 via the end sections 216,281.

#113--Column 10 line 31. Once again it is important that a ***leak proof seal*** be formed to prevent contamination or infection, and ***heat sealing*** or ***adhesive bonding techniques*** may be used.

#114--Column 10 line 52. **Sealed** against the outside.

#115--Column 10 line 54. Permits the **folded containers** 220 to overlap.

#116--Column 10 line 55. **Each container 220 defines a narrow neck region** 224 which is **sealed** to the lower portion of the associated valve. 240.

#117--Column 10 line 58. Each of the valves 240 is an on off valve which ***completely seals*** **off the** interior of the belt 210 from infection **when the valve 240 is *closed*.**

#118--Column 10 line 68-column 11 line 3. Each of the ports 250 also is in fluid communication with the central volume 300 and is **sealed to the exterior of the belt** 210 by a flange 252 on the port 250. The port valves 260 are preferably push pull valves, similar to the container valves 240.

#119--Column 11 line 7. The belt 210 should be assembled in a clean room and then sterilized prior to utilizing standard manufacturing practices for medical devices as outlined by the Food and Drug Administration.

#120--Column 11 line 14. I this way the belt is **delivered as a *single sterile unit*** ready for use.

#121--Column 11 line 16. In use the belt 210 acts as a manifold though which dialysate can be introduced and removed from the peritoneal cavity **with reduced incidence of infection.**

#122--Column 11 line 27. The valve 260 will be dry and sterile, or has been capped since its initial sterilization.

#123--Column 11 line 36. After the dialysate container has been emptied, the associated **valve 260 is closed** and the container is removed and the cap 270 is replaced. In this way the port 250 is **closed by the valve 260 before it is exposed to the atmosphere** therefore reducing contamination and infection.

#124--Column 1 line 42. The dialysate is allowed to remain in the peritoneal **cavity for a period of time** and is **then** drained from the peritoneal cavity via the belt 210 into one of containers 220. Prior to this, a selected container is unfolded and is placed within the support net 290. The associated **valve 240 is *then opened*** and dialysate flows from the central volume 300, via the conduit 230 and the valve 240 into the container 220. After the container is filled, the **associated valve 240 is *then closed*** and the filled container 220 is removed from the belt 210 by ***severing*** the neck of the bag below the valve 240. The ***severed*** **container** 220 and its contents are then discarded.

#125--Column 11 line 55. Because the container 220 is *not removed until after* the associated valve 240 has been *closed*, belt 210 is never open to atmosphere during drainage. Instead the central volume remains closed and uncontaminated.

#126--Column 11 line 60. The next batch of dialysate to be used is then connected to a second inlet **port valve 260 one which has not previously been used and the entire procedure is repeated.** In each case a **fresh input port 250 and a fresh container 220 are used**. Because no input port **250 is used twice, it is *always* a dry sterile input port valve 260 which is mated with the dialysate container.**

#127--Column 12 line 1. Furthermore, since all the drainage containers 220 are *sealed in place from the beginning*, dialysate drainage is accomplished ***without ever opening*** **the belt to atmosphere**. In this way infection associated with drainage is reduced.

#128--Column 12 line 7. The belt 210 has been designed to minimize infection of the subject from dialysate contamination either when introduced into the subject or drained.

#129--Column 12 line 14. Only after each of the ports of the containers has been used will the belt be replaced with a new belt complete **with a new set of sterile ports and folded containers.**

#130--Column 12 line 29. Like components of the two embodiments are provided with like reference numbers. "This comment refers to Figures 6-11."

#131--Column 12 line 32. As best shown in Figure 11, the belt 340 is divided by an internal partition 342 which divides the interior of the belt into two manifolds.

#132--Column 12 line 50. ***The embodiment of Figures 10 & 11 is used in much the same manner as that of Figures 6-9,*** except that for introducing dialysate into the peritoneal cavity the three way valve 370 is set n the first position which couples the inner belt catheter 334 and the indwelling catheter 330; for draining dialysate valve 370 is set in the second position, which couples the outer belt catheter 336 to the indwelling catheter 330.

#133--Column 12 line 58. A principle advantage of this embodiment is that fresh ***dialysate is not mixed*** with previously drained dialysate in the belt 340.

#134--Column 12 line 64. A third preferred embodiment of this invention is shown in Figures 12 & 13. In this embodiment belt 380 defines only a single internal volume. The belt is provided with 28 valved input output port 250 arranged along the underside.

#135--Column 13 line 7. As before, the belt 380 is ***originally a sealed sterile unit*** in which all 28 of the valves 20 are ***closed***. After the belt catheter is coupled to the indwelling catheter, dialysate is introduced into the belt from a dialysate container which is coupled to one of the input/output ports 250 under sterile conditions. **As before each port 250 *is used only once* and each valve 260 is *kept closed until after* the dialysate container has been connected.**

#136--Column 13 line 17. In this case however, the dialysate container is not removed from the port 250. After the dialysate has been drained into the peritoneal cavity. Instead the dialysate container is **left connected to the port 250 until it is time to** drain the dialysate from the peritoneal cavity. The ***without ever removing*** the dialysate container, the used dialysate is drained ***from the same container from which it came***. After the used dialysate has been returned t its container, **the associated valve 260 is closed** and ***only then is the filled dialysate container removed from the port 250***.

#137--Column 13 line 28. This embodiment provides the important advantage of low bulk and low cost. In that container need not be sealed to the belt 380 prior to use. ***More ports 250 can be easily placed around the belt 380***. Various numbers of ports may be supplied, depending on the application. The 28 ports of this third preferred embodiment will support a full week of peritoneal dialysis in which four batches of dialysate is introduced and drained daily.

#138--Column 14 line 47. Such changes and modifications can be made ***without departing*** from the spirit and scope of the present invention ***without diminishing its attendant advantages***. It is therefore intended that such changes and modification be covered by the following claims.

Applicant has provided the foregoing as a convenience for the Examiner and to highlight certain facts found in the Goldberg reference pertaining the arguments present herein. The examiner is encouraged to look at the specific citing in the Goldberg reference itself, and not solely rely on the transcription herein, in the event there may be typographical errors herein.

On page 4 of the said office action the Examiner recites "Given the context of the entire disclosure, and the emphasis on maintaining sterility of the system, it is at least implied that the fluid to be introduced into a human is sterile or aseptic "{i}n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inference which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 401 F.2d 825, 826 159 USPQ 342, 344 (CCPA 1968)."

The Examiner discredits the Examiner comments here in that the "emphasis on maintaining the sterility of the system" discredits the examiner remarks on page 4 line 11 whereby the Examiner states (supply container (20) is converted to a waist(Waste) receptacle (dirty disposal side)... Applicant contends the impossibility of converting anything to a dirty side during the period when the emphasis in on maintaining the sterility of the system. No conversion exists in the Goldberg reference. The Goldberg reference emphasizes maintaining the sterility of the system through to removal/severing step. This involves leaving the container connected to the manifold until after the container is filled with dialysate. The container is no longer useful after it is filled with dialysate, no extended useful increased life exists (supra) with the broken Goldberg container because it is destroyed and is no longer useful. It is only after the Goldberg container is removed from the manifold that the Goldberg device renders the container dirty, after the operation of filling. Applicant contends this is only one patentably distinct difference between the applied reference and the instant case because a full container has no use. It is full. A full container has no collection capacity. A broken container has no capacity for re-use. A broken container has no capacity for re-cycling as suggested in err by the Examiner.

On page 4 of the said office action the Examiner recites "Regarding claims 7 and 8, Goldberg teaches that the containers (20) are integrated into a waist (waste-supra) collection system (fig. 4) and that sterile fluid containers are recycled as waist(waste-supra)containers (col. 3, line 51-col. 4, line 53

The Examiner incorrectly drew from the Goldberg reference the following:
a) containers (20) are not integrated into a waist(waste) collection system. There is no point of consumption integration act/step involved in the Goldberg reference regarding containers (20) and an integration step. The correct factual finding on containers (20) of the Goldberg reference are that container (20) are bonded and heat sealed in place with respect to the manifolds at manufacturing and the entire Goldberg system and associated components are an integral part of the closed, sterile, dry, bonded and heat sealed, single unit, prepared by manufacturing machines and techniques prior to sterilization, prior to shipping.
b))sterile fluid containers are not recycled. Recycling involves re-preparation of a container for completely new (brand new) use. Figure 4. shows no recycling step in the Goldberg reference. Recycling involves sending the container out for refurbishment, the refurbishment would require an open step which discredits the principles of operation of the Goldberg reference. Re-cycling would occur only after the "severing" operation which is a destructive operation as would not provide requisite preparation of any useful device for the Goldberg reference and such a re-cycling operation would require an entire repeating of the said manufacturing techniques. The Goldberg reference defines nowhere, and is silent as to anything directed to repairing or fixing the destroyed containers after severing and in preparation for re-heat sealing, re bonding etc. etc. the Goldberg container is destructively removed from the sterile manifold system and is unsuitable for re-use.
c)Figure 4 shows container (20) not as sterile fluid containers, but as pre-bonded, pre heat sealed as a dry single sterile unit folded as compact receptacles before sterilization.
d)recycling is not a part of sterile collection procedure-broken container would not be re-cycled.
e)fluid waste removal would not take place with an open severed container, such a container is unsatisfactory for its intended purpose.

f)recycling in not commensurate with leaving a container attached to a sterile manifold during collection of sterile fluids.
g)recycling would happen after the container is severed.
h)recycling would occur in a separate facility, such facility would be equipped with cleaning and sterilizing facilities, and include facilities and machinery to repair the severed broken containers of the Goldberg reference and would require a re-folding operation, not anticipated or recognized by Goldberg. The Goldberg reference does not recognize or appreciate the Examiners suggestions about recycling. Recycling would necessarily occur in a facility separate from the facility in which peritoneal dialysis takes place(not the same location where dialysis is given to the patients.)

Page 4 of the said office action recites "Regarding claims 9-11, Goldberg teaches that the sterile fluid containers (clean side of a supply)(20) is converted to a waist receptacle (dirty disposal side) in a disposal chain.

The examiner incorrectly drew from the Goldberg reference the following:
a)containers (20) do not contain sterile fluids.
b)containers (20) do not deliver sterile fluids in a supply side.
c)containers (20) are a part of the single sterile unit, dry, heat sealed, bonded prior to sterilization.(no fluids a all).
d)if containers (20) were full of sterile fluids, there would be no where for the dialysate to go leaving the patients full of a fluid not intended for permanent implant.(discredits the essential purpose of Goldberg)
e)no conversion of containers (20) exists in the Goldberg reference in disposal event.
f) there is no "dirty" side recited in the Goldberg reference. Maintenance of sterility and reduction of infection is the essential principle of operation of the Goldberg reference and "all" recitations of the Goldberg reference dealing with the manifold demands specific steps and sequences to maintain sterility therein, therefore, until the severance step is made in the Goldberg reference all recitations are directed to the "sterile" and no dirty events take place. This makes it impossible for any hypothetical example created by the Examiner to have any expectation of success with regards to converting any container recited in the Goldberg reference to become a "dirty container" for any collection purposes whatsoever. The "dirty" event in the Goldberg references occurs "only after" removal of the container from the manifold, whereby the container is open(contradictory to the Goldberg principle) and after collection (bag is full while still connected to the manifold and still in its requisite sterile condition).
g)Applicant contends that there is a distinct difference in the Goldberg reference between "sterile collection" and disposal. Sterile collection, in the Goldberg reference remains a part of the sterile procedure (while connected to the manifold in the requisite sterile fashion), and is not a part of the disposal event whereas the disposal event takes place only after the containers are severed/removed from the manifold.(severed in an open unsealed, non-contained condition.) No disposal event takes place during sterile connection to the Goldberg manifold. (only sterile procedure as recited).
h)sterile collection requires "closed to atmosphere", severing requires "open top atmosphere".

Page 4 & 5 of the said office action recites "Regarding claim 12-14, Goldberg at least implies that by reusing supply containers as collection containers will reduce the amount of containers that contribute to garbage compared to using completely separate supply and collection containers, resulting in reduced waste and costs and increasing the useful life of the supply containers."

The Examiner incorrectly drew from the Goldberg reference the following:
a)Applicant contends the Examiners description of the Goldberg dialysis as a re-use is incorrectly drawn. Re-use of the Goldberg container would only naturally occur after a re-cycling event as described supra.

b)The Goldberg reference in each instance recites a single sterile operation which includes a container maintaining its sterile connection to a manifold where no reference to a re-use is made. This involves one single sterile connection until the container is removed from the manifold whereby it is then destructively removed, rendering the Goldberg containers unfit for any intended purpose. A re-use would require the Goldberg reference to be discredited into an open system resulting in the requisite infection, contamination, re-wetting and other open events the heart of the Goldberg reference requires and for which the Goldberg reference is invented to prevent. Applicant contents the Examiners suggestion of re-use changes the principles of operate as recited in the Goldberg reference.
c)The Goldberg reference recites two scenarios. One scenario where containers (20) are pre-connected. In another scenario the Goldberg reference discloses a container is left connected, during dialysis, and then after a period of time the container is receives drainage. In this scenario, where containers (20) are "omitted" no separate container would be expected to be procured for collection, no reduction of the amount of those separately procured supply chain containers contributed to the garbage exists(I.E. no separate empty collection containers from a separate supply chain exists) in the Goldberg reference.
d)if no separate empty container supply chain exists by such requisite omitting, no reduced waste, no reduced costs.
e)no elimination a supply chain would be possible by such requisite omitting.
e)there is "No completely separate empty supply chain container" as suggested by the examiner because separately produced containers are omitted and there is no such other suggestion by Goldberg that any other such containers would be reduced..
f)in the Goldberg reference, the container is left connected. To effect the supply chain container elimination of the instant case, the dialysate container would be required to be removed when the container is empty to effectively connect such a container to eliminate the supply chain costs associated with the supply of a separately produced container. (Not leaving the container left connected to the sterile manifold and then refilled)
g)the examiner incorrectly draws that in such a scenario Goldberg suggests there is a separately produced collection container which is incorrect. Goldberg has omitted any such container.
h)if no separately produced containers are contemplated in such a scenario, no supply chain costs are reduced, no waste is reduced, and in that case there is no useful life increased .
g)the container" left connected" as suggested by the Examiner is the expected procedure(for a period of dialysis time). In the instant case such separately produced container would be in operation during the period of time the container "left connected" is still attached to the manifold single sterile unit. The life of the Goldberg dialysate container is completed during the sterile procedure, left connected to the manifold with no increase in its useful life. When the Goldberg container performs the expected procedure, and is destructively removed from the manifold, there is no increase in its useful life, just its expected life, which is not at all an increase. The Applicant contends that the examiner has erred in suggesting there is an increase in the useful life of such container. If there were an increase in the Goldberg container, it would have been non-destructively removed from the manifold after the dialysate had been emptied into the peritoneum, and before collection which is equal to open and not closed.
i)There is no possibility for the increase in the expected useful life of any of the containers disclosed in the Goldberg reference because each instance of removal of the Goldberg disclosure requires a "severance" procedure leaving the container unsealed, destructively removed (somehow the bonding or heat sealing techniques at manufacturing must be destructively un-bonded or destructively un heat sealed).
j)such an expected procedure would not be expected to involve a separate supply chain container, would not be expected to involve a separately produced container, would not be expected to involve other costs to be reduced, and would not find an expected increase of useful life of such container. The

life is the life as originated by the procedure-no supply chain events occurring in this case. Such would never provide any expectation of success as defined by the Examiner.
k)applicant contends Goldberg provides an embodiment which omits the containers 20 that are pre-attached to the manifold, but this does not mean achievement of increasing the life of the other such dialysate containers is achieved in a supply chain event in accordance with the generality of the foregoing.

Page 5 of the said office action recites " Regarding claims 19-24, Goldberg teaches means (40) for sealing and/or unsealing a vacuum draw path.

The Examiner incorrectly draws for the Goldberg reference the following.
a)there is no vacuum draw path disclosed in the Goldberg reference.
b)the Goldberg reference disclosed a valve (40) as an integral part of a manifold.
c)a manifold is not a vacuum draw path.
d)a push pull valve does not possess the requisite characteristics for sealing a vacuum draw path.
e)the sealing means of the instant case discloses sealing (sealing a path from the open atmosphere condition-contrary to and discrediting the Goldberg reference)a path which is in an open condition (open to the atmosphere)(discrediting the closed requirement of the Goldberg reference) and forming a seal. Going from open to sealed.
f)The unsealing means of the instant case discloses unsealing (unsealing a path to the open atmosphere-contrary to and discrediting the Goldberg reference) path into an open condition. (open to the atmosphere)(discrediting the closed requirements of the Goldberg reference)
g)the Goldberg valve(40) only is involved in a closed valve operation(never opening the Goldberg manifold and related device to the atmosphere as is the operation carried out with the instant case.

Page 5 of the said office action recited "Claims 15 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg a applied to claims 5-14 and 19-24 above, and further in view of Weiler *et. al.* (US 4,178, 976:hereinafter "Weiler") and Kawakami et. al. (US 6,159,416 A: hereinafter "Kawakami". Goldberg is silent as the containers being made from biodegradable blow moldable materials. Weiler teaches a dispensing container comprised of blowmoldable material(col. 4 lines 48-64). Kawakami teaches blow moldable materials that are biodegradable. At the time of the invention, it would have been obvious for one of ordinary skill in the art to make the containers of Goldberg out of blow moldable materials of Weiler and Kawakami in order to provide materials that are recognized in the at as suitable for the purpose and the added benefit of decomposing landfills."
Applicant contends that Weiler et. al. is non-analogous art. Weiler is directed towards container manufacturing and not to supply chain events carried out by the customer. Also, Weiler is directed towards a different skill level in the art. Base on the generalities of the foregoing rebuttal, Applicant contends that the Goldberg reference is overcome, leaving Weiler to stand on its own in said office action. Standing alone, the Weiler reference in non-analogous.

Applicant contends that Kawakami is non-analogous art. Kawakami is directed to chemical sciences. The chemical sciences relate to the biodegradable "time taken to biodegrade in the soil" and is not directed towards any supply chain events of the instant case. Furthermore the instant case is directed at the elimination of such container, not to how long containers take to biodegrade in the soil. Applicant contents that the Goldberg reference is overcome in accordance with the generalities of the forgoing rebuttal, leaving Kawakami to stand on its own. Applicant contents Kawakami is non—analogous art.

Applicant contends that Weiler and Kawakami combined are non-analogous art, given the overcoming of the Goldberg reference and Applicant believes the combination of Weiler and Kawakami are not an obvious combination standing aloe together and based on this rebuttal.

The Applicant cancels step I of claim 7 without prejudice and with a reservation of rights to re-introduce the subject step in further RCE of CIP application pertaining to this case.

Applicant contends the foregoing rebuttal overcomes the Goldberg reference. Further the Goldberg device would not normally be used during its normal and usual operations. *MPEP 2112.02 Process claims. Prior art device anticipates a claimed process if the device caries out the process during normal operation. When the prior art device is the same as the device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801, F.2d 1324, 231 USPQ 136 (Fed. Cir 1986). Applicant contends the manifold device is nothing like the instant case. The prior art device is not the same.*

Applicant contends that all claims rejected by the Examiner in said office action are patentable, and this reply has proven, by facts presented herein such patentable distinction. The rejected claims should be re-allowed in put back in the record subject to this rebuttal.

MPEP 2143.03 All claim limitations must be taught or suggested. To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is non-obvious under 35 USC 103, then any claims depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ 1596 (Fed. Cir 1988).

Applicant recognizes certain keywords familiar t the teaching of the instant case in the examiners remarks. Applicant finds no legally recognizable heart of the Goldberg reference in said office action. Applicant believes the office action has been constructed in hindsight, which is improper.

Rejections based on 103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. *The Examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction the supply deficiencies in the factual basis of the rejection. In re Werner, 379 F.2d 1011, 1017, 145 USPQ 173, 178 (CCPA 1967), cert denied, 389 U.S. 1057 (1968). Our reviewing court has repeatedly cautioned against employing hindsight by using the appellants disclosure as a blueprint to reconstruct the claimed invention from the isolated teachings of the prior art. Grain Processing Corp. v. American Maize-Products Co. 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Ir. 1988).*

Applicant contends the closest available art (Goldberg) would likely discourage the art worker from suggesting the Examiners substitution. Goldberg teaches away. Closed teaches away from open and open teaches away from closed. *Gillette Co. v/ S.C. Johnson & son, Inc., 919 F.2d 720, 724, 16 USPQ2d 11923, 1927 (Fed. Cir. 1990) (the closest prior art reference "would likely discourage the art worker from attempting the substitution suggested").*

Applicant believes the Examiner has not met the initial threshold burden of proof because neither the suggestion nor the requisite expectation of success is founded in the prior art. *"Both the suggestion and the expectation of success must be founded in the prior art, not in the applicants disclosure". In re*

Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438 1442 (Fed. Cir. 1991) (citing In re Dow Chemical Co. 837 F.2d 469, 473, 5 USPQ 1529, 1531 (Fed. Cir. 1988).

The record is devoid of any evidence to support the combination made by the examiner. *"We remind the examiner that conclusions of obviousness must be based on facts, not generalities. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967) Cert denied, 389 US 1057 (!(^*): In re Freed, 425 F.2d 785, 788, 165 USPQ 570, 571 (CCPA 1970).*

The entire closed sterile manifold system and method of Goldberg may be omitted from the combination suggested by the examiner and the instant case will retain its function while the Goldberg reference would fail in such an omission leaving no heart left in Goldberg. *Such elimination of an element while retaining its function is indicative of unobviousness, and we find nothing in the applied prior art which would indicate otherwise. In re Fleissner, 264 F.2d 897, 900, 121 USPQ 270, 271 (CCPA 1959) it may be unobvious to omit an element while retaining its function, and Richards v. Chase Elevator Co. 159 U.S. 477, 486 1895 Comm'r of Pats. , 728, 729 ("the omission of an element in an combination may constitute invention, if the result of the new combination be the same as before").*

Applicant believes the preponderance of the evidence present in this rebuttal is overwhelming towards traversing every ground of rejection defined in the said office action. Applicant believes the claims were and continue to be allowable and are in a condition for which the applicant is legally entitled to protection.

Should the Examiner consider necessary or desirable any formal changes anywhere I the specification, claims and/or drawings, then it is respectfully asked that such changes be made by examiners amendment, if the Examiner feels this would facilitate passage of the instant case to issuance. Alternatively should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

Respectfully Submitted for the record,

MedIndica-Pak, Inc./Applicant

Jack W Romano

10/18/2006

Dated

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